Docket No.: 2294-0122PUS1

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Alfonso ROMERO et al.

Application No.: 10/594,004 Confirmation No.: 8959

Filed: September 25, 2006 Art Unit: 1616

For: PROLONGED-RELEASE COMPOSITIONS

COMPRISING TORASEMIDE AND A MATRIX-FORMING POLYMER

Examiner: A. L. Fisher

DECLARATION SUBMITTED UNDER 37 C.F.R. § 1.132

Honorable Commissioner Of Patents and Trademarks P.O. Box 1450 Alexandria, VA 22313-1450

September 3, 2010

Sir:

I, Dr. Antonio Guglietta of the Pharmaceutical Research and Development Center, Ferrer Internacional, S.A., Spain, do hereby declare the following:

I have attached a copy of my curriculum vitae to this Declaration.

I am the Research and Development Director and have worked in this field for over ten years.

I am familiar with the above referenced patent application and the area of science dealing with prolonged release compositions.

I have read and understand the subject matter of the Office Action of March 17, 2010.

The following comments are offered in support of the patentability of the instant invention.

The Examiner seems to believe that a skilled artisan would find the invention of Application No. 10/594,004 obvious because of the following references: Maegerlein et al., Azarmi et al., Pankhania et al., Berner et al. and Kaplan. I disagree.

In particular, lactose is a well known diluent which is normally used in immediate release formulation, not in controlled release formulations since it normally does not influence or control the release profile. On the contrary, it is sometimes used as a release enhancer. Scientists working in the controlled-release area would not have reasonably expected success in obtaining a controlled release formulation by using lactose.

To assist the Examiner in appreciating the instant invention, Applicants make the following points. The present invention has a formulation containing torasemide, a matrix forming polymer and lactose as the main diluent. This results in a prolonged-release formulation of toraseimide which shows a kinetic profile with fewer fluctuations and steadier levels. The percentage of lactose in the preferred formulations of the invention is about 50% of the blend (see examples 6-9). On the other hand, the matrix forming polymer is present in a small proportion in the formulation of the invention; normally less than 20% of the total composition, and more preferably from 2-5%.

To illustrate the kinetic profiles of examples of the torasemide formulations (tablets) of the claimed invention, Meyprogat[®] 90 (i.e. guar gum) at 10, 5 and 3% of the total tablet weight was tested as shown in the Table below for the 5 mg tablet dose (5 mg torasemide).

Formulation	T1604	T1704	T1804
Torasemide	5.9 %	5.9 %	5.9 %
Corn starch	36.2 %	36.2 %	36.2 %
Colloidal Silicon Dioxide	0.5 %	0.5 %	0.5 %
Meyprogat® 90	10.0%	5.0 %	3.0 %
Magnesium stearate	0.3 %	0.3 %	0.3 %
Lactose	47.1%	52.1 %	54.1 %

The following dissolution tests were performed with hydrochloric acid 0.1 N.

In comparison with Sutril[®] (Immediate release formulation), the experimental tablets showed a prolonged release behaviour starting from 3% of guar gum (batch T1804). The total

release of the active in this batch (T1804) was produced in 5 hours. Batches with 5% and 10% of the excipient (i.e. T1704 and T1604) presented a 75% active release within 5 hours with a similar kinetic profile. The following table and figure show the results of the kinetic profile of these formulations.

	Sutril 5 mg		Batch T1604		Batch T1704		Batch T1804	
Time (min)	Release per time fraction %	Release %	Release per time fraction %	Release %	Release per time fraction %	Release %	Release per time fraction	Release %
0	-	0	-	0		0	5	0
0.5	98.2	98.2	22.5	22.5	23.4	23.4	26.6	26.6
1	2.3	100.5	10.2	32.7	7.2	30.6	7.4	34.1
2	0.4	101.3	7.5	47.7	6.4	43.5	12.7	59.6
3	-0.6	100.1	5.7	59.0	5.7	54.8	12.8	85.1
4	-0.3	98.9	3.7	73.9	6.1	79.1	3.1	97.5

Table. Release values (with HCl 0.1N) for tablets manufactured with Meyprogat® 90.

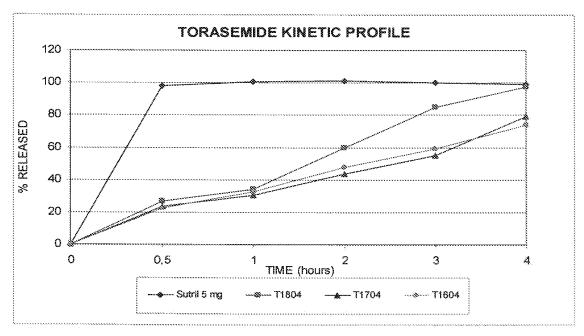


Figure. Release profiles (with HCl 0.1N) of Torasemide from Meyprogat® 90matrix tablets.

The percentage of lactose in the experiments is above 45% with respect of the blend. The amount of guar gum is less than 10% of the amount of lactose.

Therefore, it is my opinion that the invention as described in the current claims would not have been obvious to a skilled artisan in view of the cited references. Neither do I believe that a skilled artisan would have had a reasonable expectation of success if they had tried to combine the cited references in order to obtain the instant invention.

The undersigned hereby declares that all statements made herein based upon knowledge are true, and that all statements made based upon information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED: September 3, 2010

Dr. Antonio Guglietta

<u>Curriculum Vitae:</u> <u>Antonio Guglietta, MD, PhD</u> (Updated Jul 2010)



Personal

Place of Birth Sperlonga (LT), Italy

Date of Birth March, 8 1956

Citizenship Italy

Languages Italian (fluent)

English (fluent) Spanish (fluent) Catalan (basic) French (basic)

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E-mail: antonioguglietta@ureach.com (home)

Education

1982: University "La Sapienza", Rome, Italy

M.D. degree (graduated with honors)

<u>Thesis:</u> Synthetic peptides related to the Dermorphins: Synthesis and biological activities of the shorter homologues

and of analogues of the heptapeptides

1988: University "La Sapienza", Rome, Italy

Ph.D. (Gastroenterology: graduated with honors)

Thesis: Central nervous regulation of gastric acid secretion.

Role of Bombesin, Dermorphin and Calcitonin

1999 Management Development Program

University of Michigan, Business School

Ann Arbor, MI, USA

2010: University of Navarra IESE Business School:

Executive Development Programa (PDD)

Residency and interships

1982 Resident

Hospital "Umberto I", Rome, Italy

(Surgery)

1982 Resident

Hospital "Dono Svizzero", Formia, Italy

(Gynecology and Obstretics)

1982 Resident

Hospital "Umberto I", Rome, Italy

(Internal medicine)

1983 Internship

Hospital "Nuovo Regina Margherita", Rome, Italy

(Gastroenterology)

1983 Internship

Hospital "San Gallicano", Rome, Italy

(Dermatology & Venerology)

Board Certification

1982 Italian Board Certification

Post graduate training

1991 Gastrointestinal pharmacology

American Gastroenterological Association

New Orleans, LA, USA

1993 Mucosal diseases of the gastrointestinal tract

American Gastroenterological Association

Boston, MA, USA

1993 Gastrointestinal endoscopy

European Society of Gastrointestinal Endoscopy

Barcelona, Spain

1994 Clinical Immunology in gastroenterology and hepatology

American Gastrointestinal Association

New Orleans, LA, USA

1995 Evolving Concepts in Gastrointestinal and Liver Diseases

American Gastrointestinal Association

San Diego, CA, USA

Professional Organizations

1986 -American Society for Neuroscience 1986 -International Brain Research Organization (IBRO) 1987 -American Association for the Advancement of Science 1987 -New York Academy of Science American Endocrine Society 1988 -1988 -1991 North Carolina Society for Neuroscience American Gastroenterological Society 1991 -International Brain-Gut Society 1992 -International Union of Pharmacology - GI Section 1994-1995 -Gastroenterology Research Group 1996 -Worldwide Hungarian Medical Academy

Scientific Offices held

May 1996-July 1998 Member of the Communications Committee of International Union of Pharmacology (IUPHAR) - GI Section

July 1998-July 2002 Secretary of the International Union of Pharmacology (IUPHAR) – GI Section

Oct 1996-July 2000 Secretary of the International Brain-Gut Society

1995-DateFounder and President of "International Researchers in Gastroenterology & Hepatology" a non-profit organization devoted to foster scientific interactions among investigators working in the area of gastroenterology and hepatology around the world.

Manuscript and grants review activity

- Gastroenterology
- British J. Pharmacology
- Eur. Journal Pharmacology
- J. Pharm. Exp. Ther.
- Can. J. Physiol. Pharmacol.
- Life Sciences
- VA grant reviewer
- Am. J. Physiology

Positions

1980-1982 Intern,

Institute of Medical Pharmacology, University "La Sapienza", Rome, Italy

1982-1984 Post doctoral Fellow

Institute of Medical Pharmacology, University "La Sapienza", Rome, Italy

1984-1987 Visiting Fellow,

Peptide Neurochemistry Group

National Institute of Environmental Health Sciences

Research Triangle Park, N.C., USA

1987-1988 Visiting Associate

Peptide Neurochemistry Group

National Institute of Environmental Health Sciences

Research Triangle Park, N.C., USA

1988-1990 Visiting Scientist

Clinical Biochemistry Dept. of Biochemistry

Glaxo Research Laboratories Research Triangle Park, NC, USA

1990-1991 Visiting Scientist

Immunopathology Dept. of Therapeutics

Parke-Davis Pharmaceutical Research Division of Warner-Lambert Company

Ann Arbor, MI, USA

1991-1992 Research Associate

Immunopathology Dept. of Therapeutics

Parke-Davis Pharmaceutical Research Division of Warner-Lambert Company

Ann Arbor, MI, USA

1992- 2000 Senior Research Associate

Immunopathology
Dept. of Therapeutics

Parke-Davis Pharmaceutical Research Division of Warner-Lambert Company

Ann Arbor, MI, USA

2000- Date R&D Director

Grupo Ferrer Internacional

Barcelona, Spain

Awards

1997-1998

1984-1987 Visiting Fellowship the Fogarty International Center, National Institutes of Health, Bethesda, Maryland, U.S.A. 1986 Travel Grant provided by the Endocrine Society for the purpose of attending the 68th Annual Meeting of the Endocrine Society. 1988 Grant provided by the Organizing Committee of International Conference on Gastroenteric Biology for the purpose of attending such Conference 1991-1997 Name included in: Who's Who in Science and Engineering, 1st Ed. 1991, 2nd Ed. 1994-1995, 3rd Ed. 1996-1997. Marquis Who's Who. 1992-1994 Name included in: Who's Who in America, 47th edition. 1992, 48th Edition 1994. Marquis Who's who. 1994-1998 Name included in: Who's Who in the Midwest. 24th edition. 1994, 25th Ed. 1996, 26th Ed. 1998, Marquis Who's who 1994 International Men of the Year in recognition of his services to Research Published by International Biographical Centre, Cambridge, England Name included in: Who's Who in the world,12th 1995-1996 edition. Marquis Who's who 1995-1996.

Name included in Who's Who in Medicine and Health

care, 1st Ed. Marquis Who's Who. 1997-1998

Selected invited lectures

Jun. 1989 3rd International congress of Videoendoscopy

Abano Terme, Italy Title of the presentation:

Quantitative endoscopy: evaluation of ulcer

re-epithelization

Jun. 1992 3rd International symposium on experimental

ulcer disease: "Stress, Basic and Clinical Research;

Gastrointestinal Protection,

Zagreb, Croatia

Title of the presentation:

Possible clinical use of peptide growth factors in the

GI tract: perspectives and obstacles

Nov. 1994 5th International symposium on GI research:

Zagreb, Croatia.

Title of the presentation:

Preclinical evaluation of compounds with possible therapeutic activity in inflammatory bowel disease

May 1995 University of California San Diego

Cancer Center San Diego, CA, USA Title of presentation:

Activity of EGF in the GI tract: Preclinical and clinical data

June 1996 IBC meeting on IBD

Philadelphia, PA USA Title of presentation:

Activity of EGF in animal models of IBD

Apr 1997 University of Bologna, Italy

Institute of Hematology Title of presentation:

"Can we protect the GI tract from chemiotherapics-induced

damage in hematologic patients ? Role of EGF"

Apr. 1997 University of Padua, Italy

Institute of Internal Medicine

Title of presentation:

" New strategies for the pharmacotherapy of inflammatory

gastrointestinal diseases"

Bibliography

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 Melchiorri P., Falconieri Erspamer G., Erspamer V., Guglietta, A., De Castiglione R., Faoro F., Perseo G., Piani S., Santangelo F. SYNTHETIC PEPTIDES RELATED TO DERMORPHIN. II. SYNTHESIS AND BIOLOGICAL ACTIVITIES OF NEW ANALOGUES. Peptides 3:745-748, 1982.

3. **Guglietta, A.**, Strunk C.L., Irons B.J., Lazarus L.H. CENTRAL NEUROMODULATION OF GASTRIC ACID SECRETION BY BOMBESIN-LIKE PEPTIDES. Peptides 6 (Suppl. 3):75-81, 1985.

 Lazarus L.H., Wilson W.E., Gaudino G., Irons B.J., Guglietta, A. EVOLUTIONARY RELATIONSHIP BETWEEN NON MAMMILIAN AND MAMMILIAN PEPTIDES.

Peptides 6 (Suppl. 3): 295-307, 1985.

5. Improta G., **Guglietta, A.**THE ROLE OF CAUDATE NUCLEUS IN DERMORPHIN-INDUCED CATALEPSY IN RATS.
Peptides 6 (Suppl. 3): 161-164, 1985.

 Guglietta, A., Irons B.J., Lazarus L.H., Melchiorri P. STRUCTURE-ACTIVITY RELATIONSHIP OF DERMORPHIN ON GASTRIC SECRETION. Endocrinology 120 (5):2137-2147, 1987.

7. **Guglietta, A.**, Irons B.J., Lazarus L.H. INTERACTION BETWEEN BOMBESIN AND PROSTAGLANDINS IN THE CONTROL OF GASTRIC SECRETION. Ann. New York Acad. Sci. 547: 486-487, 1988

8. Lazarus L.H., Guglietta, A., Wilson W.E., Grimes L.M., Irons B.J. and Yajima H. NEUROMEDIN B: PHYSIOLOGICAL AND PHARMACOLOGICAL PERTUBATIONS.

Ann. New York Acad. Sci. 547: 404-414, 1988

J. Neurol. Methods 23: 161-172, 1988

9. Lazarus L.H., Irons B.J., Grimes L.M., Wilson W.E., Guglietta, A., Yajima H. ASSESSMENT OF NEUROMEDIN B POLYCLONAL ANTIBODIES AS MOLECULAR PROBE IN NEURAL TISSUE.

10. Guglietta, A., Irons B.J., Lazarus L.H. EFFECT OF BOMBESIN, DERMORPHIN AND SALMON CALCITONIN ON GASTRIC ACID SECRETION IN RATS. Meth. Find. Exp. Clin. Pharmacol. 10 (8):481-485, 1988

11. Guglietta, A., Irons B.J., Lazarus L.H. EFFECT AND MECHANISM OF ACTION OF LITHIUM CHLORIDE ON GASTRIC ACID SECRETION. Gastroenterology 95: 1454-1459, 1988

12. Guglietta, A.

Regolazione Nervosa Della Secrezione Acida Gastrica: Ruolo Della Bombesina, Dermorfina e Calcitonina. Doctoral Thesis. Ph.D. program in Gastroenterology, University of Rome", La Sapienza ", Italy, July 1988.

13. Lazarus, L.H., Guglietta, A., Wilson, W.E., Irons, B.J., de Castiglione R. DIMERIC DERMORPHIN ANALOGUES AS MU-RECEPTOR PROBES ON RAT BRAIN MEMBRANES. CORRELATION BETWEEN CENTRAL MU-RECEPTOR POTENCY AND SUPPRESSION OF GASTRIC ACID SECRETION Journal Biological Chemistry 264 (1): 354-362, 1989

14. Lazarus, L.H., Wilson, W.E., de Castiglione, R.,

Guglietta, A.

DERMORPHIN GENE SEQUENCE PEPTIDE WITH HIGH AFFINITY AND SELECTIVITY FOR DELTA OPIOID RECEPTORS. Journal Biological Chemistry 264 (6): 3047-3050, 1989.

15. Guglietta, A., Irons, B.J., Lazarus, L.H., de Castiglione, R., Melchiorri, P. DIMERIC DERMORPHIN PEPTIDES: CENTRAL ADMINISTRATION SUPPRESSES GASTRIC ACID SECRETION THROUGH INTERACTION WITH MU-TYPE OPIOID RECEPTOR Meth. Findings Exp. Cli. Pharmacol. 11 (11): 663-670, 1989.

16. Guglietta, A., Nardi, R.V. and Lazarus L.H. INDOMETHACIN (i.c.v.) REVERSES THE INHIBITORY ACTION OF PEPTIDES ON GASTRIC SECRETION. European J. Pharmacology 170 (1-2): 87-90, 1989.

17. Lazarus, L.H., Wilson, W.E., **Guglietta, A.** and de Castiglione R.

DERMORPHIN INTERACTION WITH RAT BRAIN OPIOID RECEPTORS: INVOLVEMENT OF HYDROPHOBIC SITES IN THE BINDING DOMAIN.

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- 19. **Guglietta, A.**, Hervada, T. and Nardi, R.V.
 THE USE OF A THYMIDINE INCORPORATION ASSAY IN THE
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 INDOMETHACIN-INDUCED GASTRIC DAMAGE IN RATS.
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POSSIBLE CLINICAL USE OF PEPTIDE GROWTH FACTORS IN THE GI TRACT: PERSPECTIVES AND OBSTACLES.

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- 22. **Guglietta A.**, and Lesch CA. EFFECT OF h-EGF AND h-EGF 1-48 ON HISTAMINE-STIMULATED GASTRIC ACID SECRETION IN RATS AND MONKEYS
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 COLONIC DAMAGE IN RATS.
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CLINICAL APPLICATIONS OF EPIDERMAL GROWTH FACTOR Eur. J. Gastroenterology and Hepatology 1995: 7: 945-950

26. M. Romano, CA Lesch, KS Meise, M. Veljaca, B. Sanchez, ER Kraus, R. Boland, A. Guglietta, RJ Coffey

INCREASED GASTRODUODENAL CONCENTRATION OF TRANSFORMING GROWTH FACTOR α IN ADAPTATION TO ASPIRIN IN MONKEYS AND RATS.

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27. Sizemore, N., Dudeck, RC., Barksdale, CM., Nordblom, GD., Mueller, WT., McConnel P., Wright, DS., **Guglietta, A**., Kuo, BS.

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Methods and Finding in Exp and Clin Pharmacol. 21 (2), 99-104, 1999

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SYNTHESIS, STRUCTURE-ACTIVITY RELATIONSHIPS AND IN-VIVO EVALUATION OF SUBSTITUTED DI-T-BUTYLPHENOL AS A NOVEL CLASS OF POTENT SELECTIVE AND ORALLY ACTIVE PGHS-2 INHIBITORS, 1. THIAZOLONE AND OXAZOLONE SERIES.

J. Medicinal Chemistry 42 (7), 1151-1160, 1999

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- 36. CA. Lesch, ER Kraus, **A. Guglietta**3-ISOBUTYL GABA PROTECTS AGAINST EXPERIMENTALLY INDUCED DAMAGE IN THE UPPER GASTROINTESTINAL TRACT BY A CENTRALLY MEDIATED MECHANISM OF ACTION Journal of Digestive Protection 1 (2), 57-64, 2000
- 37. Epstein, JB, Gorsky M, **Guglietta A**, Le N., Sonis, S. THE CORRELATION BETWEEN EPIDERMAL GROWTH FACTOR LEVELS IN SALIVA AND THE SEVERITY OF ORAL MUCOSITIS DURING OROPHARYNGEAL RADIATION THERAPY Cancer: 89 (11): 2258-65, 2000
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 Drugs of the Future 26 (4), 335-341, 2001
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 J. Chemother. 13(5): 555-62, 2001
- 41. Lirussi, F. **A. Guglietta**IMPAIRED NATURAL KILLER CELL CYTOTOXIC ACTIVITY IN CHRONIC HEPATITIS C VIRAL INFECTION: A CONTROLLED STUDY
 Current Therapeutic Research
- 42. M. Guerrero, C. Albet, A. Palomer, **A. Guglietta**DRYING IN PHARMACEUTICAL AND BIOTECHNOLOGICAL INDUSTRIES
 Food Science and Technology International: Vol. 9 (3), 237-243, 2003

- 43. Improta G, Carpino F, Petrozza V, **Guglietta A**, Tabacco A, Broccardo M. CENTRAL EFFECTS OF SELECTIVE NK(1) AND NK(3) TACHYKININ RECEPTOR AGONISTS ON TWO MODELS OF EXPERIMENTALLY-INDUCED COLITIS IN RATS. Peptides: Vol. 24 (6), 903-911, 2003
- 44. Tarragó, C. Alemany, C., Palacin, C., Terencio, J., **Guglietta, A.** NOVES TECNOLOGIES EN LA RECERCA D'ANTIMICROBIANS Antimicrobians 55, 67-80, 2004
- 45.Carrillo-Munoz, A.J., **Guglietta, A**., Palacín, C., Casals, J., Del Valle, O., Guardia, C., Rodriguez, V., Quindos, G. IN VITRO ANTIFUNGAL ACTIVITY OF SERTACONAZOLE COMPARED WITH NINE OTHER DRUGS AGAINST 250 CLINICAL ISOLATES OF DERMATOPHYTES AND SCOPULARIOPSIS BREVICAULIS. Chemotherapy 50 (6), 308-313, 2004
- 46. Falcó J.L., Lloveras M., Buira I., Teixidó J., Borrell J.I., Terencio J., Palomar A., **Guglietta**

DESIGN, SYNTHESIS AND BIOLOGICAL ACTIVITY OF ACYL SUBSTITUTED 3-AMINO-5-METHYL-1,4,5,7-TETRAHYDROPYRAZOLO [3,4-b]PYRIDIN-6-ONES AS POTENTIAL HYPNOTIC DRUGS. Eur. J. Med. Chem. 40, 1179-1187, 2005

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- 48. Contelles, J.M., León, R., De los Rios, C., **Guglietta, A.**, Terencio, J., López M.G., García, A.G., Villarroya, M.

 NOVEL MULTIPOTENT TACRINE-DIHYDROPYRIDINE HYBRYDS, WITH IMPROVED ACETYLCHOLISTERASE INHIBITORY AND NEUROPROTECTIVE ACTIVITIES, AS POTENTIAL DRUGS FOR THE TREATMENT OF ALZHEIMER'S DISEASE.

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